IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Momma, et al	**Examiner:**	Brian E. Pellegrino
Ser. No.	10/630,355	**Group Art Unit:**	3738
Title:	**ENDOVASCULAR IMPLANT FOR THE INJECTION OF AN ACTIVE SUBSTANCE INTO THE MEDIA OF A BLOOD VESSEL**		
Filed:	July 30, 2003	**Date:**	February 16, 2007

STATEMENT ACCOMPANYING REQUEST FOR PRE-APPEAL BRIEF REVIEW

A pre-appeal brief request for review is hereby made. The Applicants maintain that the Examiner has not established a prima facie case of obviousness of the pending claims. Claims 1, 3-13, and 26-29 stand rejected as being unpatentable over U.S. Patent 6254632 to Wu et al. ('Wu') under 35 U.S.C. § 103(a). Claims 14 and 15 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Wu in view of U.S. Pat. No. 6,287,628 to Hossainy et al. ("Hossainy") The Applicants maintain that the Examiner has mischaracterised the content of the cited prior art and has used hindsight in rejecting the claims.

The Examiner maintains that Wu discloses "a stent having a base body with a plurality (col. 8, lines 50-56) of microdevices 200 that project from the implant surface to form a microcannula 218 on the outer surface to engage a vessel wall (col. 6, lines 13-17)." The Examiner also maintains that the description of the cover of the stent of Wu could also support the interpretation of the structures of Wu having the same length as the microcannulae of the present invention. However, this interpretation is contrary to the explicit teachings of Wu regarding the length of the microcannulae. As previously stated in the response filed 8 September 2006 (page 8), Wu clearly discloses a "lip height" of 10-80 μm (Wu, col. 11, lines 65-67).

Other explicit statements by Wu also indicate that the Examiner's interpretation of the "microcannulae" length of Wu is incorrect. As previously stated in the response of 8 September 2005, the term used by Wu to describe the structures in question, "craters," further indicates that Wu does not intend for these structures to penetrate into the wall of the blood vessel, but rather only to "engage the lumen of the passageway." (Column 6, line 15). As stated in the response of 27 February 2006, because the "lumen" of a blood vessel is actually the inner open space or cavity of the blood vessel, Wu can only mean that the craters 200 contact ("engage") the wall of the blood vessel at its inner surface.

The Examiner further indicates that the intended use of the microcannulae in the claims carries no weight absent a distinguishing structure. However, such a structure is explicitly provided by the claims. Regarding claims 3 and 4, the Examiner specifically indicates that the Applicants have not indicated that the recited microcannulae lengths of 150 μm or 180 μm provide any advantage, solve a stated problem or are used for any particular purpose. The Examiner's assertion is clearly incorrect. As stated in the response of 8 September 2006 (page 9) as well as the responses of 29 March 2006 (pages 8-9) and 8 September 2005 (page 5), Wu provides a stent that only delivers a therapeutic substance to the inside surface of a blood vessel. Wu does not provide any teaching or suggestion of delivery of a therapeutic substance to the vessel media, that is, beneath the endothelium, the basal lamina and the inner elastic membrane of the blood vessel by a microcannula that penetrates the blood vessel wall, as taught by the present application (paragraph 0034 and Fig. 1.) Instead, Wu only provides stents that "engage the lumen of the passageway … to help prevent the stent from slipping out of the treatment site." (Column 6, lines 15-17.) Therefore, the Applicants respectfully maintain that the Examiner has misconstrued the scope and content of the prior art to conclude that one of skill in the art would have been motivated to modify the teachings of Wu to arrive at the invention recited in claim 1.

Because the Examiner has not established a suggestion or motivation to modify Wu, or a reasonable expectation of success in modifying the teachings of Wu to arrive at the present invention, the Applicants maintain that a prima facie case of obviousness has not been established and that the current rejection of the claims is based on the impermissible use of

hindsight to combine elements found or thought to be found in the prior art to arrive at the present invention. Withdrawal of the rejection of claim 1 under 35 USC § 103(a) is respectfully requested. Likewise, the Applicants also maintain that claims 3-15 and 26-29, which depend from and include all the limitations of claim 1, also patentably distinguish over the cited prior art.

Furthermore, because claims 1, 3-11, 14, 15, and 26-29 are believed to be in condition for allowance and are believed to be generic for all species, rejoinder of the non-elected species claims, claims 16-25, is also requested. The issuance of a Notice of Allowance is likewise requested.

The final Office Action was mailed on 16 November 2006. No extension of time is believed to be required with the filing of this paper. However, in the event that the need for a petition for an extension of time has been overlooked, a conditional petition for the necessary extension of time is hereby made with this appeal and request for pre-appeal brief review. The Commissioner is authorized to charge any fee required with the filing of this response or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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